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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,944	02/01/2002	Thomas J. Schall	019934-003210US	8775

20350 7590 02/23/2004

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,944	SCHALL ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-62* is/are pending in the application.

4a) Of the above claim(s) *50-52,56-58,61 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-49,53-55 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/16/02, 09/03/02, and 09/02/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group VI, claims 47-59 Applicant's response to the restriction requirement, dated December 18, 2003 is acknowledged. The traversal is on the ground(s) that claim 47 is a generic claim that links the claims in Groups VI, VII, and VIII. This is not found persuasive, because Groups VI and VII are drawn to two patentably distinct inventions. While claim 47 links the two inventions, the active method steps recited in claims 60-61, the recited method step is not required for the invention that is recited in Group VII. Further, the invention of Group VIII is drawn to collecting CMV from tissues, whereas the inventions of Group VI-VII are drawn to blood.

The Examiner admits to have omitted to include the linking claims form paragraph, see below. Thus, should claim 47 be found allowable, the restriction requirement as to the linked invention, claims 60-62 of Groups VII-VIII, will be withdrawn.

The following should have been included in the restriction requirement "Claim 47 link(s) inventions VI-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 47. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or

divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01."

Thus, in view of the correction made in this office action, the requirement is deemed proper and is therefore made FINAL.

Status of Claims

2. The amendment filed 12/18/2003 has been entered. Claims 1-46 are canceled. Claims 47-62 are currently pending. Claims 50-52, 56-58, and 61-62 are withdrawn from examination in view of Applicant's election of Group VI. Claims 47-49, 53-55,and 59 are currently under examination.

Specification

3. The title of the invention is now: Methods For Assessing Cytomegalovirus Mutations, as requested by Applicant in Applicant's December 18, 2003 response.

4. The disclosure is objected to because of the following informalities: It appears that line 16 of page 13 is incomplete.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 47-49, and 54-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to US28 ligands that detect and assess mutation in CMV. However, the specification does not contain a disclosure that pertains to ligands that would identify one or any mutation in CMV.

To provide adequate written description and evidence of possession of a claimed invention, the specification must provide or identify compounds that can identify one or any mutation in CMV. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the specification does not contain any of the listed factors. Accordingly, in the absence of such evidence, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed

above, the skilled artisan cannot envision compounds and/or ligands that can identify one or any mutations in CMV, and therefore conception is not achieved until reduction to practice has occurred. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

7. Claims 47-49, 52-55, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative

skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wrigtht*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

The quantity of experimentation necessary to practice the claimed invention would be immense since Applicant has not taught or provided any guidance that would enable one of ordinary skills in the art to make or use the claimed invention.

The nature of the claims are directed to an ex vivo and an in vivo method of assessing mutations of cytomegalovirus with the detection of the absence or presence of mutations cytomegalovirus in CMV infected cells with compounds that binds to CMV. The compounds that are identified in the later claims include US28 ligands and a compound having CAS registry No. of 74611-28-2, 20229-30-5, 13448-22-1, and 4789-68-8—which are recited in claims 53 and 59. The ex vivo method requires the withdrawal of blood from a CMV infected patient and flowing the blood into a collector that comprises a compound that binds to CMV. The in vivo method requires the use of an implant device that is comprises a compound that binds to CMV and is in contact with the blood of the patient infected with CMV.

Meanwhile, the breadth of the claims encompasses any CMV US28 ligand, any compound that binds to CMV, and the detection of the presence or absence of CMV with only one CMV infected cell.

However, Applicant has not shown or demonstrated how the compound that binds to CMV can detect the presence or absence of mutations, and how that detection would lead to the assessment of mutations in cytomegalovirus. In addition, Applicant has not shown that the compound is capable of differentiating between wild type and mutated CMV. It appears that there is no nexus between the compound that binds to CMV, detecting mutations of CMV, and the assessment of mutations in CMV.

In addition, Applicant has not shown that binding and recognition between CMV and the compound to which it binds to is exclusive to each other. In other words, Applicant has not shown that the compound binds only to CMV and not other pathogens or naturally occurring cells. This is important to demonstrate that the sample collected in the claimed method to detect the presence or absence of CMV contains on CMV infected cells and nothing else. This would aid in the accuracy of the detection and eventually to the assessment of mutations in CMV.

Further, as mentioned, the nature of the invention is an ex vivo and in vivo use of claimed invention. First, concerning the ex vivo use of the claimed invention, Applicant's claimed method requires the withdrawal of blood from a CMV infected patients and flowing the blood through a collector that contains a compound that binds to CMV, which implies that the blood is continuously withdrawn from the patient. There is no mention in the specification of i) how much blood would be necessary to determine the presence or absence of mutations; ii) what would be done to compensate for loss of blood from the patient where the blood is continuously withdrawn; iii) how to extract the CMV cells that binds to the compound from the blood that flowed through the collector;

and iv) if the withdrawn blood is cycled back into the infected patient-- which now supposedly no longer contain CMV infected cells that are infected of CMV, how would the compound that did not react with CMV or fragments thereof or the blood that was in contact with the compound that binds to CMV affect cell cycle, the patient's chemistry, and other bodily functions.

Now, concerning the in vivo use of the claimed method via an implant device, the specification does not contain any guidance concerning i) the duration which the implant device should remain in order to detect and assess mutations in CMV, ii) how the compound affects cell cycle, the patient's chemistry, and other bodily function because some of the cited compounds intended for use in the claimed method are know to have an anti-psychotic affect; and iii) how the collected CMV infected cells can be used to detect and assess mutation of CMV.

The specification is not enabling for the use of any of the above listed compounds in the claimed invention, the same is true of the prior art. The prior art teaches that COS-7 cells transfected with US28-bound I-MCP-I and I-RANTES are ligands for US28 (Kuhn et al.). The prior also teaches that compounds with CAS registry No. 74611-28-2, 20229-30-5, 13448-22-1, or 4789-68-8 have an anti-psychotic affect in humans. The prior art does not teach the claimed invention. It does not also teach the use of the compounds or US28 ligands to attract CMV. In addition, Applicant has not provided any evidence that the claimed invention is useful in the assessment of mutations in CMV. There is also no reduction to practice the claimed method in the disclosure.

For these reasons, it is determined that an undue quantity of experimentation would be required of the skilled artisan to make and use the invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le

Emily Le

Shanon Foley

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